

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: Tarara et al.                                    | Group Art Unit: 1618                             |
| Application No: 10/750,934<br>Confirmation No: 1899                    | Examiner: Schlientz, Leah H                      |
| Filed: December 31, 2003   | Attorney Docket No: 53279-US-CNT<br>(NV.0101.00) |
| Title: PHARMACEUTICAL<br>FORMULATION WITH AN<br>INSOLUBLE ACTIVE AGENT | May 3, 2010<br>San Francisco, California         |

**REPLY BRIEF**

**VIA ELECTRONIC FILING**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Answer mailed on March 3, 2010, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby maintains the appeal to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

**Certificate of Transmission**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, facsimile transmitted to the U.S. Patent and Trademark Office at (571) 273-8300, or electronically submitted via EFS on the date shown below:

By:   
Melanie Hitchcock

Date: May 3, 2010

### ***Status of Claims***

Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105 and 109-111 are presently pending in the case. Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105 and 109-111 have been finally rejected. The rejection of each of claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105 and 109-111 is hereby appealed.

Claims 1-37, 40, 42, 43, 45, 46, 57, 59, 61, 69-102 and 106-108 have been cancelled.

***Grounds of Rejection to be Reviewed on Appeal***

Appellant continues to request review of the Examiner's following grounds of rejection:

Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105 and 109-111 have been rejected under 35 U.S.C. §103(a) as being unpatentable over WO 01/85136 to Weers et al (hereinafter Weers et al), as evidenced by US 2002/0177562 to Weickert et al (hereinafter Weickert et al), 2000 Journal article to Weidmann et al (hereinafter Weidmann et al) and WO 00/01365 to Didriksen (hereinafter Didriksen).

Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105 and 109-111 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Application No. 11/187,757.

## ***Argument***

Appellant believes each of claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105 and 109-111 is improperly rejected and is therefore allowable for the reasons set forth in Appellant's Appeal Brief filed on January 25, 2010. The present Reply Brief is being filed to specifically address some of the issues raised by the Examiner in the Examiner's Answer mailed on March 3, 2010. The comments herein are merely supplemental to the arguments made in the Appeal Brief and are not meant to replace those arguments.

### The rejections under §103(a) are improper

The Examiner's rejection of independent claim 38, for example, under 35 USC §103(a) as being unpatentable over Weers et al as evidenced by Weickert et al, Weidmann et al and Didriksen, continues to be improper.

As discussed in the Appeal Brief, Weers et al does not teach or suggest a pharmaceutical formulation with insoluble active agent particles in a phospholipid matrix, wherein the particulates do not comprise lactose. Throughout the vast majority of Weers et al, the reference teaches particulates where a ***solution*** of an active agent (as opposed to ***particles*** of active agent) is dispersed within a phospholipid matrix. The Weers et al particulates do not, in general, comprise insoluble active agent particles. The one exception to this teaching is Example V where Weers et al discloses budesonide particles that are in a phospholipid matrix. However, in this example, the budesonide is combined with lactose (see page 12 lines 1-4).

Claim 38 explicitly excludes lactose-containing particles from its ambit. To account for Weers et al's teaching of the use of lactose, the Examiner first contended that it would have been obvious to eliminate "lactose carrier particles" from the Example V version of Weers et al. However, there are no lactose carrier particles in Example V of Weers et al. Instead, the lactose in Weers et al Example V is within the particulates

themselves. Accordingly, the “modification” posited by the Examiner was no modification at all and would not have resulted in the invention of Appellant’s claim 38.

In the Reply Brief, the Examiner corrected this error and now contends that it would have been obvious to one of ordinary skill in the art to use something other than lactose in the particulates of Example V. However, the Examiner provides no evidence for this allegedly-obvious modification. Instead, the Examiner appears to be relying on an “obvious to try” rationale, such as that formulated in KSR International v. Teleflex, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). However, the present case is not controlled by KSR for several reasons. For example, unlike in KSR, the modification presently proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 1, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Actually, the artisan would have seen more of a benefit in not doing so, since a lactose-containing version is successfully exemplified in the reference. Furthermore, the unpredictable nature of changing excipients in pharmaceutical formulations distinguishes the present case from the straight-forward mechanical substitutions in KSR. For at least these reasons, the rejection of claim 1 is not supported by the KSR decision, and claim 1 is allowable over the references cited.

The Examiner then goes on to improperly rely on another Weers et al Example. In the Reply Brief, the Examiner now points to Weers et al Example VII to show particulates not containing lactose. However, the Example VII particulates are not particulates that contain insoluble active agent particles. As can be seen from Weers et al page 29 lines 7-9, in this Example, the budesonide is dissolved in the feedstock, as opposed to the suspended particles in the Example V version. Thus, Example VII of Weers et al would be solid solution particulates and would bear very little relevance to the issues under appeal.

The balance of the independent claims similarly distinguishes Weers et al and the other applied references.

## Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments and the arguments provided in the Appeal Brief. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: May 3, 2010

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